



Standard Operating Procedures		
<b>SOP #109.3 Revision 3</b>	<b>TITLE: Staff Processing of Submissions</b>	Effective Date: 3/24/2017
Approved By: OIRB Director	Signature 	Date 3/24/2017
Approved By: IRB Chair	Signature 	Date 4/21/2017

**PURPOSE**

To describe policies and procedures for how Office of the Institutional Review Board (OIRB) staff conduct intake and pre-review of new submissions to the UNM IRB.

**REVISIONS FROM PREVIOUS VERSION**

Revise time line for withdrawal

**POLICY**

In the environment of research, openness and honesty are indicators of integrity and responsibility. The efficiency and effectiveness of the IRB is supported by administrative procedures that ensure that IRB members not only have adequate time for thorough assessment of each proposed study, but that the documentation they receive is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

**RESPONSIBILITIES**

Execution of SOP: OIRB Staff

**PROCEDURE**

1. OIRB Staff assess daily new submissions through IRBNet. The submission will first go through an intake process where OIRB Staff assess the submission for basic elements (e.g. submission application, expiration date, accuracy of information in IRBNet, status of PI compliance, etc.). Should a project be lapsed, OIRB staff will follow procedures described in the Lapse of IRB Approval SOP.
2. After intake is complete, submissions are assigned to the analysts who conduct a pre-review before assigning submissions to a reviewer.
3. Submissions are processed by analysts on a first-come first-served basis. Submissions may be processed more quickly at the discretion of OIRB Staff (e.g. administrative reviews, studies approaching expiration, short funding time lines, etc.)
4. Pre-review consists of assessing the completeness of each submission, checking for all required documents and signatures, reviewing documents for consistency, as well as determining if sufficient information has been provided for IRB review of criteria at 45 CFR 46.111 and/or 21 CFR 56.111.
5. OIRB staff screen the IRB application to ensure coordination with other university committee reviews as outlined in the applicable standard operating procedures or to ensure compliance with pertinent federal requirements. Examples of screening include, but are not limited to, the items listed below.



- OIRB staff screen to determine whether the PI addressed off-site issues following procedures outlined in the Off Site Research SOP.
  - If the research involves prisoners, the study is appropriately flagged and OIRB staff send the protocol to a prisoner representative for review.
  - OIRB staff determine whether the U.S. Department of Education has funded the research and/or whether the proposed research involves surveying children in the public schools. If so, OIRB staff inform the IRB of specific U.S. Department of Education requirements.
  - OIRB staff determine whether the research is supported by other federal agencies which have specific requirements such as the U.S. Department of Defense or U.S. Department of Energy. If so, OIRB staff inform the IRB of specific agency requirements for the review and conduct of the research.
  - OIRB staff determine whether research involves vulnerable subjects and/or sensitive types of research/procedures (e.g. HIV screening). If so, OIRB staff ensure that appropriate expertise will be present at the convened meeting, if undergoing full committee review.
  - OIRB staff screen the application to determine if the investigator has answered “yes” on the questions in the Research Financial Interest Disclosure Form. If so, OIRB staff and the IRB follow procedures outlined in the Researcher Conflict of Interest Coordination SOP.
  - If the researcher indicates Institutional Biosafety Committee (IBC) approval is necessary, the researcher must include IBC provisional approval materials. OIRB staff check to ensure that the PI has submitted the materials. OIRB staff may check with the Institutional Biosafety Officer for advice. The Institutional Biosafety Officer has the authority to make the final decision as to whether the project requires IBC approval.
6. In the instance that OIRB staff have questions about a submission, a “clarifications requested” message will be sent to the researcher(s) through IRBNet and the IRBNet package will be unlocked to allow for changes. When the researcher(s) provide clarifications, they will “mark revisions complete” which will relock the package and allow for continued processing of the submission.
  7. If a submission requires clarifications, OIRB staff will not schedule the submission for review until clarifications are addressed. If no response is received within 30 days, OIRB staff will withdraw the submission without IRB review.
  8. Once the pre-review process has been completed, OIRB staff will assign the submission for review. For new projects, the analyst makes a preliminary risk assessment and assigns the project for either exempt, expedited, or full board review (the reviewer(s) will make the final review level determination). For Amendments and Continuing Reviews, the submission will be assigned for review based on the previously determined risk assessment, review level, and current status of the project. If appropriate, the submission will be sent for administrative review (e.g. administrative changes or closures). If research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review except in limited circumstances as described in expedited categories (8) and (9).
  9. When the reviewer has completed the review, OIRB staff will assess the reviewer documents for completeness and consistency. Should the analyst have questions, the reviewer will be contacted. Once the review is verified as complete, the analyst will send a letter to researchers with the IRB determinations.